

## PATENT

REMARKS

In the Office Action, claims 1-5 and 8-26 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,456,882 to Schloss.

In the Office Action, claims 6 and 7 are rejected under 35 U.S.C. §103(a) as being unpatentable over Schloss in view of U.S. Patent Number 6,584,355 B2 to Stessman.

In response thereto, claims 1, 3, 11, 12, 19, and 20 have been amended. Accordingly, claims 1-26 are pending. Following is a discussion of the patentability of each of the pending claims.

Independent Claim 1

Claim 1 recites a method of monitoring the performance of an automatic capture verification feature in a cardiac stimulation device. The method comprises monitoring the number of backup stimulation pulses delivered at a high-energy output and storing the number of backup stimulation pulses delivered at the high-energy output setting, monitoring the number of primary stimulation pulses delivered at each of a plurality of stimulation output settings and storing the number of primary stimulation pulses at the respective output settings. At least one of the plurality of stimulation output settings of the primary stimulation pulses is at the high-energy output setting. The method further comprises comparing the stored number of backup stimulation pulses to the stored number of primary stimulation pulses to evaluate the performance of the automatic capture verification feature, wherein the step of comparing comprises selectively comparing the stored number of backup stimulation pulses delivered at the high-energy output setting with the stored number of primary stimulation pulses delivered at the high-energy output setting.

The Schloss reference discloses a system and method for performing automatic capture/threshold detection in an implantable cardiac stimulation device. According to the Schloss reference, existing systems periodically determine a threshold stimulation energy level, and a working stimulation energy level is then set by increasing the threshold

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stimulation energy level by a fixed or preprogrammed safety margin. In certain circumstances, the safety margin may be insufficient, resulting in either frequent threshold level determinations or loss of capture. To avoid these situations, the Schloss reference discloses various embodiments which periodically increase and/or decrease the safety margin according to the performance of the stimulation device, i.e., based upon the frequency of capture.

The Schloss reference does not disclose or suggest selectively comparing the stored number of backup stimulation pulses delivered at the high-energy output setting with the stored number of primary stimulation pulses delivered at the high-energy output setting to monitor the performance of the automatic capture verification feature. In column 12, lines 12-20, the Schloss reference discloses the following methods to determine the performance of the stimulation device: 1) comparing the number of non-captured cycles (B) to the number of captured cycles (C), 2) comparing the number of non-captured cycles (B) to the number of total paced counts (B + C), 3) comparing the number of non-captured cycles (B) to the total number of cardiac cycles (B + C + I), and 4) comparing number of non-captured cycles (B) to a specified period of time to determine a loss-of-capture rate. No where does the Schloss reference disclose or suggest selectively comparing the stored number of backup stimulation pulses delivered at the high output setting with the stored number of primary stimulation pulses delivered at the high-energy output setting.

The Stessman reference is directed to measuring current drain or charge depletion for implantable medical devices. In one embodiment, an oscillating output is provided with a frequency of oscillation that is dependent on a pulse generator current  $I_{PG}$ . An oscillation count is provided or determined for the oscillating output, and the pulse generator current  $I_{PG}$  is determined based on the oscillation count over a period of time. Charge depletion of a battery is determined by continuously summing the oscillation count over successive periods of time.

No where does the Stessman reference disclose or suggest selectively comparing the stored number of backup stimulation pulses delivered at the high-energy output setting with the stored number of primary stimulation pulses delivered at the high-energy output setting to evaluate the performance of the automatic capture verification feature. In the Stessman reference, the degree of battery depletion is determined by summing the oscillation count over successive periods of time such that primary stimulation pulses are not distinguished from backup stimulation pulses.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

#### Dependent Claims 2-10

Claims 2-10 depend from claim 1 and are similarly patentable. Furthermore, in accordance with the American Inventors Protection Act, the Schloss reference does not qualify as prior art for the rejection of claims 6 and 7 under 35 U.S.C. §103(a) via 35 U.S.C. §102(e) because the present application has been filed on or after November 29, 1999 and the subject matter of the Schloss reference and claims 6 and 7 were, at the time the invention was made, subject to an obligation of assignment to the same organization (see section entitled "Obligation of Assignment to the Same Organization"). Accordingly, the Schloss reference no longer qualifies as prior art under 35 USC §103(a) via 35 USC §102(e). Accordingly, it is respectfully submitted that these claims are in condition for allowance.

#### Independent Claim 11

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 11 is in condition for allowance.

#### Dependent Claims 12-18

Claims 12-18 depend from claim 11 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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Independent Claim 19

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 19 is in condition for allowance.

Dependent Claims 20-26

Claims 20-26 depend from claim 19 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Obligation of Assignment to the Same Organization

Ronald Tamura, an attorney of record for the present application, states that Application Serial Number 09/964,225 and U.S. Patent Number 6,456,882 B1 to Schloss were, at the time the invention of Application Serial Number 09/964,225 was made, owned by Pacesetter, Inc. or subject to an obligation of assignment to Pacesetter, Inc.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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